

database. Baseline demographics, HbA1C, co-morbidities, health care utilization, pharmacy copayment, and concomitant followup antidiabetic medications were controlled. Costs were evaluated using actual paid claims by health insurance, adjusting for inflation to the most current year value. **RESULTS:** Patients at baseline had same mean age 54 years, 44 vs. 52% female, baseline HbA1C 9.3 vs. 8.9%, access to endocrinologist 36 vs. 46%, average number of oral antidiabetic agents 2.3 vs. 2.0, patients with medical insurance claims for hypoglycemia 3.2 vs. 4.3%, Charlson comorbidity score for overall comorbidities 0.64 vs. 0.82, and 6-month total health care costs \$8,797 vs. \$12,924 in glargine vs. NPH initiator groups, respectively. Adjusted 1-year mean HbA1C was 8.05 vs. 8.51% ($\delta = -0.45$, $p = 0.0036$) and 2-year mean HbA1C was 8.03 vs. 8.37% ($\delta = -0.33$, $p = 0.0099$) for glargine and NPH, respectively. At end of 2 years, 16.6% NPH initiators dispensed glargine prescriptions while 2.7% glargine initiators dispensed NPH prescriptions. Adjusted rate of patients per quarter in the first year with medical claims for hypoglycemia was 1.7 vs. 2.9% ($\delta = -1.2\%$, $p = 0.0559$) and 2-year quarterly rate was 1.55 vs. 2.51% ($\delta = -0.96\%$, $p = 0.0139$). Adjusted 1-year total health care costs were \$16,184 vs. \$21,104 (quarterly $\delta = -\$1,034$, $p = 0.0372$) and 2-year costs was \$30,032 vs. \$42,208 (quarterly $\delta = -\$1,522$, $p = 0.0029$). **CONCLUSION:** Initiation of insulin glargine, relative to NPH, was associated with sustained improvements in glycemic control with lower rate of medically claimed hypoglycemia and lower total health care expenditures in patients with T2DM.

PDB15

LOWER RATE OF HOSPITALIZATION IN SUBSEQUENT YEAR OF INSULIN GLARGINE VS NPH INITIATION IN INDIVIDUALS WITH TYPE 2 DIABETES (T2DM)

Leahy J¹, Rhoads GG², Wei W³

¹University of Vermont College of Medicine, Burlington, VT, USA,

²University of Medicine and Dentistry of New Jersey, Piscataway, NJ, USA,

³sanofi-aventis, U.S. Group, Bridgewater, NJ, USA

OBJECTIVES: To compare 1-year health care utilization and costs in patients initiating insulin glargine vs NPH. **METHODS:** Patients with T2DM (03/2001-C03/2005) who failed oral agents and initiated insulin glargine or NPH were evaluated using the Integrated Health Care Information System, a US managed care health plan database. Patients were continuously enrolled with managed care health plans for ≥ 6 months before and 12 months after insulin initiation. Propensity score matched NPH to glargine initiators by baseline demographics, HbA1c, co-morbidities, health care utilization, and pharmacy copayment. Conditional logistic regression, McNemar's test, and paired t-test were used to compare subsequent utilizations/ costs between two insulin groups. Costs were paid by health insurance, adjusting for inflation to the most current year value in database. **RESULTS:** Matched sample ($n = 1,468$) was 46% female, mean age 54.6 yrs., A1C 9.2%, Charlson Comorbidity Index (CCI) 0.69, metformin-use 77.6%, sulfonylureas 77.6%, and thiazolidinedione 56%. Before matching, glargine initiators were more likely than NPH initiators to be female, had higher HbA1c, CCI, more use of TZD, sulfonylurea and statins, fewer visits to an endocrinologist, higher out-of-pocket drug copayment, lower total health care utilization and associated costs (except diabetes medications). After propensity score matching, no differences remained between matched pairs. During 12-month follow-up, glargine initiators showed a lower hospitalization rate (OR:0.73, 95%CI [0.57-0.94], $P = 0.0124$) while outpatient and emergency service utilization was not statistically different between groups. Number needed to treat with glargine was 17 (95% CI:

9-59) to avoid hospitalization for a patient. For the same follow-up period, glargine use on average cost \$532 vs. \$293 for NPH ($P < 0.0001$) and \$2097 vs \$1820 for all antidiabetic medications ($P < 0.0001$). **CONCLUSION:** Initiation of insulin glargine is associated with lower rate of hospitalization compared to NPH in individuals with T2DM. This clinical benefit is achieved with a modest increase in pharmacy expenditures for treating diabetes.

PDB16

GLYCEMIC CONTROL WITH INSULIN GLARGINE PLUS GLULISINE VERSUS PREMIX IN REAL WORLD PRACTICES—A RANDOMIZED, PROSPECTIVE, OBSERVATIONAL STUDY

Levin P¹, Zhang Q², Mersey J¹, Lee F¹, Bromberger L¹, Bhushan M³, Jhaveri M⁴, Bhushan R³

¹Model Clinical Research, Baltimore, MD, USA, ²sanofi-aventis,

Bridgewater, NJ, USA, ³Metabolic Center Of Louisiana Research

Foundation, Baton Rouge, LA, USA, ⁴Rutgers University, Piscataway, NJ, USA

OBJECTIVES: Despite extensive use of basal-bolus and premixed analog insulin therapy, real-world comparative effectiveness of the regimens has not been determined. **METHODS:** Patients with Type 2 diabetes at two US endocrinology practice centers were randomized to insulin glargine plus glulisine (GLAR/GLU, $n = 106$) or analog premix ($n = 91$). Subsequent to randomization, patients continued treatment following center's usual practice with no additional therapeutic protocols. Data collected at 0, 3, 6 and 9 months included A1C, hypoglycemia, insulin dose, concomitant medications, and therapy change. Medication costs were estimated using published average wholesale price. **RESULTS:** Treatment groups were comparable at baseline with mean age 56 years, 46% male, 59% Caucasian, and 38% African-American, duration of diabetes 13 years, HbA1C 9.25%, and BMI 35.8 kg/m². About 70% patients used oral hypoglycemic agent(s) during 4 months before randomization, 88% used insulin with mean daily dose of 71IU, and 29% had chart records for hypoglycemia. Mean follow-up time was 183 days. 1 patient (1%) randomized to GLAR/GLU switched to premix therapy relative to 9 (10%) randomized to premix switched to GLAR/GLU. In ITT analysis, adjusted mean follow-up HbA1C was 6.98% in GLAR/GLU vs. 7.57% in premix ($\delta = -0.59\%$, $p = 0.009$) and HbA1C reduction was 2.27% (95% CI: 1.63-2.91) vs. 1.68% (1.20-2.16). Mean number of concomitant oral anti-diabetic agents were 0.94 vs. 1.22 ($\delta = -0.28$, $p = 0.041$). Mean daily insulin dose was 74IU vs. 85IU ($\delta = -11$, $p = 0.267$). Hypoglycemia was recorded in charts for 36% vs. 43% ($\delta = -7\%$, $p = 0.374$) patients in GLAR/GLU vs. premix. Daily costs for all anti-diabetic medications were \$9.8 in GLAR/GLU vs. \$11.9 in premix ($\delta = -\$2.1$, $p = 0.036$). Treatment costs per 1% HbA1C reduction during follow-up period (183 days) were \$790 for GLAR/GLU vs. \$1,296 for premix. **CONCLUSION:** In real world practices, glargine plus glulisine, relative to analogue premix, produces improved glycemic control with lower total diabetes medication costs.

PDB17

MEDICAL COSTS AMONG INDIVIDUALS WITH DIABETES, HYPERTENSION OR HYPERCHOLESTEROLEMIA

Lage MJ¹, Boye KS²

¹HealthMetrics Outcomes Research, LLC, Groton, CT, USA, ²Eli Lilly

and Company, Indianapolis, IN, USA

OBJECTIVES: Diabetes, hypertension and high cholesterol are all prevalent in the United States. The purpose of this research is

to compare medical costs in a managed care setting for individuals with the following diagnoses: diabetes mellitus (DM), hypertension (HYP), and hypercholesterolemia (HC). In so doing, this research will allow payers to understand the comparative resource implications of these common conditions. **METHODS:** Data from the i3 LabRx Database were used for this study. Adult patients who were diagnosed with DM (N = 2,815), HYP (N = 6,073), or HC (N = 11,442) were included in the study. Differences among the three groups were examined using chi-square statistics for categorical variables and t-statistics for continuous variables. Two-year cost comparisons among the cohorts were conducted using a multivariate regression that controlled for patient characteristics, general health status and comorbid conditions. **RESULTS:** Compared to the DM cohort, the HYP cohort was significantly older and less likely to be male, while the HC cohort was more likely to be male. Individuals diagnosed with HYP or HC had significantly lower total direct two-year medical costs compared to those in the DM cohort (−\$4,588, $p < 0.0001$; and −\$9,062, $p < 0.0001$ respectively) as well as significantly lower inpatient costs (−\$3,640, $p < 0.0001$; −\$13,463, $p < 0.0001$), and outpatient prescription drug costs (−\$1,518, $p < 0.0001$; −\$2,823, $p < 0.0001$). In addition, patients in the HYP or HC cohorts were found to have significantly lower disease-specific total direct two-year medical costs (−\$1017, $p < 0.0001$; −\$4941, $p < 0.0001$, respectively) compared to individuals in the DM cohort. **CONCLUSION:** Results from this study indicated significant differences in demographic characteristics and comorbidities among individuals diagnosed with DM, HYP, or HC. These differences translated into significant cost differences, with patients diagnosed with DM experiencing both higher total medical costs and higher disease-specific medical costs than individuals diagnosed with either HYP or HC.

PDB18

THE COST-EFFECTIVENESS OF PIOGLITAZONE COMPARED WITH ROSIGLITAZONE: AN ECONOMIC EVALUATION PROJECTING RESULTS FROM A CLINICAL STUDY INTO THE FUTURE USING A VALID AND RELIABLE ECONOMIC MODEL FROM A THIRD PARTY PAYER PERSPECTIVE IN THE USA

Minshall M¹, St. Charles M¹, Pandya B², Baran RW²

¹IMS Health, Noblesville, IN, USA, ²Takeda Global Research and Development Center, Inc, Deerfield, IL, USA

OBJECTIVES: Thiazolidinediones (TZDs) were first introduced in the late 1990s as adjunctive oral therapy for patients with type 2 diabetes mellitus (T2DM). The comparative economic values of TZD therapeutic options currently available in the US marketplace are not well characterized. We estimated the cost-effectiveness of pioglitazone compared with rosiglitazone in treating T2DM consistent with AMCP cost-effectiveness guidelines. **METHODS:** Clinical efficacy and baseline parameters were taken from Goldberg RB et al, 2005, and entered into a previously validated, Markov-based economic model for T2DM. The model was used to project long-term improvements in clinical and economic outcomes comparing pioglitazone with rosiglitazone. A series of Markov constructs simulated the progression of diabetes-related complications (cardiovascular, neuropathy, renal and eye disease). Transition probabilities and HbA1c-dependent adjustments were derived from published epidemiological studies. Costs of T2DM complications were taken from published sources. Drug acquisition costs for pioglitazone and rosiglitazone were assumed to be \$4.91/day and \$4.18/day, respectively (WAC prices, 2007), and remained constant. A time horizon of 35 years was used, with costs and clinical outcomes discounted at 3% per annum. Univariate sensitivity analyses

were conducted to test robustness of the base case cost-effectiveness ratio scenarios. **RESULTS:** The incremental life-years and quality-adjusted life years gained for pioglitazone versus rosiglitazone were 0.180 and 0.129 years, respectively, at an overall increased cost of \$3241 per patient over the simulation period. Therefore, the incremental cost-effectiveness ratios were \$17,981/LY and \$25,219/QALY gained, respectively, in our base case analysis. One-way sensitivity analyses demonstrated that with variation in key input parameters (discount rates, HbA1c, lipid effects, etc.); cost-effectiveness findings were most sensitive to changes in HbA1c and high density lipoprotein (HDL) effects. **CONCLUSION:** Our economic modeling analysis suggests that pioglitazone delivers superior economic value when compared to rosiglitazone due to improved clinical outcomes specifically related to HDL effects.

PDB19

THE COST-EFFECTIVENESS OF PIOGLITAZONE COMPARED WITH SITAGLIPTIN: AN ECONOMIC EVALUATION USING A VALIDATED ECONOMIC MODEL FROM A THIRD PARTY PAYER PERSPECTIVE IN THE USA

Minshall M¹, St. Charles M¹, Pandya B², Baran RW², Bron M²

¹IMS Health, Noblesville, IN, USA, ²Takeda Global Research and Development Center, Inc, Deerfield, IL, USA

OBJECTIVES: Sitagliptin was the first dipeptidyl peptidase 4 (DPP-IV) inhibitor to be approved by the FDA. The comparative economic value of thiazolidinediones (TZDs) and the new (DPP-IV) class of oral diabetes medications has not been studied. We estimated the cost-effectiveness of pioglitazone compared with sitagliptin in treating T2DM over a lifetime horizon in the US setting. **METHODS:** Clinical efficacy parameters for pioglitazone were extracted from Goldberg RB et al, 2005. Sitagliptin parameters were extracted from Aschner P et al, 2006 and assumed no lipid effects. Both were entered into a validated economic model for T2DM. A series of Markov constructs simulated the progression of diabetes-related complications (cardiovascular, neuropathic, renal, and ophthalmic). Transition probabilities and HbA1c-dependent adjustments were derived from published epidemiological studies. Mean baseline HbA1c was comparable (7.6% for pioglitazone, 8.04% for sitagliptin). Costs of diabetes complications were taken from published sources. Drug acquisition costs for pioglitazone and sitagliptin were assumed to be \$4.91/day and \$4.86/day, respectively (WAC prices, 2007), and continued over the duration of the simulation. The time horizon was 35 years and costs were discounted at 3% per annum. Univariate sensitivity analyses were conducted to test the robustness of the base case cost-effectiveness ratios. **RESULTS:** The incremental life-years (LY) and quality-adjusted life years (QALYs) gained for pioglitazone versus sitagliptin were 0.111 and 0.075 years, respectively, at an overall increased total health care cost of \$359 per patient over the specified time horizon. Therefore, the incremental cost-effectiveness ratios (ICER) were \$3236/LY and \$4804/QALY gained for pioglitazone versus sitagliptin. Sensitivity analyses demonstrated that the base case cost-effectiveness ratios were most sensitive to changes in HbA1c and high density lipoprotein (HDL) values. **CONCLUSION:** Our economic modeling analysis suggests that pioglitazone may deliver superior economic value when compared to sitagliptin due to improved HbA1c and cardiovascular outcomes at reasonable incremental cost.